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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,941	06/22/2001	Mark L. Gonzalgo	47675-21	8405

22504 7590 11/28/2003

DAVIS WRIGHT TREMAINE, LLP
2600 CENTURY SQUARE
1501 FOURTH AVENUE
SEATTLE, WA 98101-1688

EXAMINER

MYERS, CARLA J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,941	GONZALGO ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 11-17 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

With respect to claims 11-17, the specification as originally filed does not provide basis for the concept set forth in the newly added claims of "labeled dNTPs" or dNTPs that are labeled with radiolabels, fluorescent labels, phosphorescent labels, enzymic labels, mass labels detectable by mass spectrometer or combinations thereof. The specification as originally filed provides basis only for ³²P-dNTPs. The specification also states that fluorescent probes may be utilized in the disclosed method, but does not teach using fluorescent dNTPs. There is no basis in the specification to support the amendment to the claims to recite generically that the dNTPs are labeled or to recite that the dNTPs are labeled with any radiolabel, fluorescent label, phosphorescent label, enzymic labels or mass labels.

With respect to claims 17 and 19, the specification as originally filed does not provide basis for the concept of primers which are "the bisulfite-converted equivalents thereof." The specification does not define this phrase and does not refer to primers in terms of being bisulfite-converted equivalents. It is not clear as to what is intended to be encompassed by this phrase. However, it appears that this phrase includes variants of

the recited sequence which have been treated with sodium bisulfite or which have modified at cytosine residues or which have been otherwise modified in their sequence. There is no basis in the specification for such modified primers or for primers which are "equivalents" of SEQ ID NO: 1-12. The specification teaches modifying the genomic DNA with sodium bisulfite, but does not teach modifying the primers with sodium bisulfite.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 19 are indefinite over the recitation of "the bisulfite-converted equivalents thereof" because this phrase lacks proper antecedent basis. Furthermore, it is unclear as to what is intended to be encompassed by this phrase because the phrase is not defined in the specification or in the art and is not referred to in the specification. It is unclear as to whether such primers include primers which have been treated with sodium bisulfite or primers in which a uracil has been substituted for some or all of the cytosines in a primer. It is unclear as to what makes the primer an equivalent and it is unclear as to what degree of sequence identity or complementarity are shared between the primers of SEQ ID NO: 1-12 and "bisulfite-converted equivalents."

Double Patenting

3. Claims 18 and 20-22 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 7 and 9-11 of prior U.S. Patent No. 6,251,594. This is a double patenting rejection.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-17, and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,251,594. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '594 are inclusive of methods of determining the DNA methylation status of a genomic DNA sample by assaying for the methylation state at the cytosine residue of the CpG dinucleotide sequences by measuring the incorporation of labeled dNTPs. The present claims recite generally that the dNTPs are labeled, whereas the claims of '594 specifically recite labeling the dNTPs with ³²P. Accordingly, the presently claimed method encompasses detecting the use and detection of ³²P-labeled dNTPs.

Additionally, both the present claims and the claims of '594 encompass Ms-SNuPE primers comprising SEQ ID NO: 1-12.

5. Claims 11-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-22 of copending Application No. 10/109,725. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '941 are inclusive of methods of determining the DNA methylation status of a genomic DNA sample by assaying for the methylation state of more or more CpG dinucleotide sequences within a sequence that hybridizes to any one of SEQ ID NO: 1-12.


This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. This phone number will be changed after January 13 to (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. This number will be changed after January 22 to (571) 272-0782. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
November 25, 2003


CARLA J. MYERS
PRIMARY EXAMINER